IP 04-1502-C H/K Novelty v Gonzales [3]
Judge David F. Hamilton Signed on 8/14/06

NOT INTENDED FOR PUBLICATION IN PRINT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

NOVELTY, INC.,	)	
	)	
Plaintiff,	)	
vs.	)	NO. 1:04-cv-01502-DFH-TAB
	)	
KAREN TANDY,	)	
JOHN ASHCROFT,	)	
ALBERTO GONZALES,	)	
	)	
Defendants.	)	

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

NOVELTY, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
KAREN TANDY, Administrator, U.S. Drug Enforcement Administration, and ALBERTO GONZALES, Attorney General of the United States, each in their respective capacities,	)	CASE NO. 1:04-cv-1502-DFH-TAB
	)	
Defendants.	)	

ENTRY ON DEFENDANTS' MOTION TO DISMISS

Plaintiff Novelty, Inc. brought this case against the Administrator of the U.S. Drug Enforcement Administration ("DEA") and the Attorney General of the United States.[1] Novelty claims defendants violated the Administrative Procedure Act ("APA") and Novelty's due process rights by sending a letter to Novelty as part of a larger agency compliance effort regarding the proper storage and transportation of certain List I chemicals (which can be used as precursors in methamphetamine production). Novelty argues that the letters amount in substance to unilateral rulemaking, without notice and an opportunity for affected parties to comment.

[1]After this action was filed, Alberto Gonzales replaced John Ashcroft as the Attorney General of the United States. Pursuant to Fed. R. Civ. P. 25(d)(1), the court hereby substitutes Attorney General Gonzales for former Attorney General Ashcroft as a defendant in this action.

Defendants have moved to dismiss each of Novelty's claims, arguing that this court lacks subject matter jurisdiction. As explained below, the court finds that it has jurisdiction over plaintiff's challenge to what it contends is one of a series of letters by which DEA has effectively amended its existing regulations. Plaintiff has not challenged a final "determination,", "finding," or "conclusion" by the DEA after formal procedures that develop a record suitable for judicial review, so 21 U.S.C. § 877 does not apply to require that any judicial review be pursued only in a Court of Appeals. Taking plaintiff's factual allegations at face value, and giving plaintiff the benefit of favorable inferences, the challenged agency letter may nevertheless amount to a final agency action suitable for judicial review. To hold otherwise would open a path for the defendants to substitute informal letter-writing for the formal process of notice and comment rulemaking. Perhaps more important, to hold otherwise would insulate the letters from effective judicial review unless and until an affected party is willing to act contrary to the DEA's stated position and to risk severe civil and even criminal penalties. The court therefore denies defendants' motion.

Standard for Dismissal

As the party invoking federal court jurisdiction, Novelty has the burden of showing that the court has jurisdiction over this matter. *Lac Du Flambeau Band of Lake Superior Chippewa Indians v. Norton*, 422 F.3d 490, 502 (7th Cir. 2005). On defendants' motion to dismiss, the court must take all well-pleaded facts as true and draw all reasonable inferences in the plaintiff's favor. On issues of

subject matter jurisdiction, the court may also look beyond the jurisdictional allegations in the complaint and weigh conflicting evidence. *Alicea-Hernandez v. Catholic Bishop of Chicago*, 320 F.3d 698, 701 (7th Cir. 2003); *Long v. Shorebank Development Corp.*, 182 F.3d 548, 554 (7th Cir. 1999). Because the defendants have thus far successfully resisted plaintiff's discovery requests, however, the court treats this jurisdictional challenge as one limited to the pleadings, so the plaintiff receives the benefit of its allegations and favorable inferences.

Factual Allegations

As part of its business, Novelty sells "List I" chemicals that are subject to statutory and regulatory requirements administered by the DEA. In May 2004, Dan E. Raber, Diversion Group Supervisor of the Indianapolis Office of the DEA, sent a letter to Novelty pertaining to the overnight storage and distribution of List I chemicals. Compl. Ex. A. The letter included three scenarios that it stated were aimed at "clarifying" the requirements for proper storage of such chemicals. Novelty alleges that the standards articulated in Raber's letter and others like it, see Compl. Ex. B, substantially alter existing regulations pertaining to storage and distribution of List I chemicals. The result, Novelty contends, amounts in substance to the final agency action of rulemaking without notice and comment in violation of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, and the Due Process Clause of the Fifth Amendment to the U.S. Constitution. Plaintiff also argues that the "new rules," even if procedurally valid, are unenforceable as

arbitrary and capricious. Novelty filed this action for declaratory and injunctive relief in September 2004.[2]

Defendants have moved to dismiss. The motion originally advanced four arguments, two pertaining to jurisdiction and two to the merits of the dispute between the parties. After disputes over discovery, Magistrate Judge Baker denied certain of Novelty's requests for discovery. *Novelty, Inc. v. Tandy*, 2005 WL 2253599 (S.D. Ind. Sept. 1, 2005), *aff'd*, Docket No. 58 (S.D. Ind. Feb. 3, 2006). In the course of the discovery disputes, the defendants withdrew their merits-based arguments in their motion to dismiss. Accordingly, this entry is limited to the defendants' arguments regarding this court's subject matter jurisdiction.

Discussion

I. *Application of 21 U.S.C. § 877*

Defendants contend first that a district court may not hear this case because subject matter jurisdiction lies exclusively with a Court of Appeals pursuant to 21 U.S.C. § 877, which provides:

[2]The complaint also sought a declaration that a subpoena issued to Novelty by the DEA in Arkansas was invalid. The Arkansas subpoena was withdrawn on August 8, 2005, see Docket No. 44, Ex. 1, and Novelty then withdrew its challenge to that subpoena. See Docket Nos. 44 at 16, 55 at 10. The DEA's Indianapolis office then issued a different subpoena to Novelty. Novelty has not challenged the new subpoena.

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

The subchapter in which § 877 is codified does not specifically define the meaning of the critical terms "determinations," "findings," or "conclusions." Defendants argue that, taking the facts alleged in Novelty's complaint as true, Novelty appeals a final determination, finding, or conclusion of either the Attorney General or the DEA, so that an appeal is proper only in a federal Circuit Court of Appeals.[3]

Novelty argues that it does not challenge any "final determinations, findings," or "conclusions of the Attorney General," and that it challenges the letter as improper rulemaking, which is governed by 21 U.S.C. § 821 rather than § 877. Section 821 authorizes the Attorney General to "promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals."

[3]Defendants also argue under § 877 that Novelty has failed to file a timely claim since it did not file its complaint until four months after the agency action at issue, well outside of the thirty-day limit provided in § 877. The court therefore may not transfer the case to a Court of Appeals under 28 U.S.C. § 1631.

As with any statute, interpretation of § 877 properly begins with its language. See *Silvernail v. Ameritech Pension Plan*, 439 F.3d 355, 358 (7th Cir. 2006). The critical question is the scope of the statutory terms "determinations, findings, and conclusions."

The context of the language is important. See, *e.g.*, *Richards v. United States*, 369 U.S. 1, 11 (1962) (provision of statute should not be read "in isolation"; court should also "look to the provisions of the whole law, and to its object and policy"), quoting *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1956). The context shows that the Controlled Substances Act ("CSA") uses the terms determinations, findings, and conclusions quite specifically, authorizing the Attorney General to make "findings, determinations and conclusions" through procedures that give affected persons some form of notice, an opportunity to be heard, an opportunity to develop a formal record of the agency action, and a later opportunity for judicial review of that decision based on the formal record.

Section 811(a) provides in relevant part that the Attorney General may add a substance or drug to a schedule provided in the act if, among other actions, he makes "findings" in accordance with § 812(b). Rulemaking pursuant to § 811 must be performed on the record after the opportunity for a hearing conducted in accordance with the APA. Section 824 allows the Attorney General to suspend or revoke an entity's registration to manufacture, distribute, or dispense a controlled substance "upon a finding" that the registrant has committed one of several

enumerated actions, such as falsifying an application. This section requires that the action be taken only after an order to show cause and a proceeding before the Attorney General conducted in accordance with the APA.

Section 823 governs the registration of entities that manufacture, distribute, and dispense controlled substances. It requires the Attorney General to register such an entity after making a "determination" that doing so would be consistent with the public interest (or prohibits registration after a "determination" that doing so would be inconsistent with the public interest). Section 824 provides that, as with revocation and suspension of registration, the Attorney General cannot deny registration without offering the opportunity for proceedings conducted in accordance with the APA.

Accordingly, the key statutory terms in § 877 – "final determinations, findings, and conclusions" – are tied to other specific statutory provisions that establish formal procedures that provide an opportunity to develop a record of agency decision-making and an opportunity for judicial review of that record. The Raber letter to plaintiff Novelty does not fit into any of those categories, and there has been no opportunity for Novelty to develop a record before the agency.

Applicable case law on the jurisdictional reach of § 877 is sparse and in conflict, but the most persuasive view is that § 877 does not apply where there has been no formal finding, conclusion, or determination based on a record that

provides a meaningful basis for judicial review. In *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1078-79 (D. Or. 2002), *aff'd in part and reversed in relevant part*, 368 F.3d 1118 (9th Cir. 2004), *aff'd on merits*, *Gonzales v. Oregon*, 546 U.S. —, 126 S.Ct. 904 (2006), the district court considered whether an Attorney General directive stating that "prescribing, dispensing, or administering federally controlled substances" to assist an individual's suicide violated the CSA exceeded the scope of his power delegated by the CSA. The district court first considered whether the directive amounted to the kind of determination, finding, or conclusion of the Attorney General that, under § 877, placed jurisdiction of the challenge solely in a Court of Appeals.

The district court found that the directive was not within the scope of § 877, explaining that § 877 applied to "situations where the Attorney General makes a quasi-judicial determination that resolves disputed facts in a specific case after some level of administrative proceedings," citing §§ 811, 823 and 824 summarized above. 192 F. Supp. 2d at 1085. The court also explained that § 877 might theoretically apply to formal rulemaking because the action produces an administrative record that could be reviewed by an appellate court. Where there was no administrative record pertaining to the directive, and where the only record regarding the determination was being produced in the district court, the district court found it had jurisdiction, citing *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991). *Oregon v. Ashcroft*, 192 F. Supp. 2d at 1086.

McNary v. Haitian Refugee Center, Inc. offers useful guidance here. There the Supreme Court held that the district court had jurisdiction over the plaintiffs' due process claims regarding procedures of the Immigration and Naturalization Service. The Supreme Court explained that a court presumes that Congress legislates with the knowledge of the well-settled premise of statutory construction favoring the provision of judicial review of administrative action. In light of this presumption and the limited review provided by the statute at issue in *McNary*, § 210 of the Immigration and Nationality Act ("INA"), the Supreme Court found jurisdiction existed in the district court for several reasons.

First, because judicial review of administrative action is commonly limited to the agency's record, barring jurisdiction in the district court would have prevented meaningful review in that case, where one of the primary attacks was that the agency procedures did not allow applicants to assemble adequate records. *McNary*, 498 U.S. at 496-97. Second, where plaintiffs had produced evidence of unfair agency practices that would have been irrelevant to the agency proceedings but were relevant to their claims, allowing review only in the Court of Appeals would prevent the kind of factfinding and record development characteristic of district court proceedings. *Id.* In general, the Court explained, "statutes that provide for only a single level of judicial review in the courts of appeals are traditionally viewed as warranted only in circumstances where district court factfinding would unnecessarily duplicate an adequate administrative record." *Id.* at 497 (internal quotations omitted). In a case where factfinding was essential,

allowing review only in the Court of Appeals would effectively deny review. *Id.* Applying this reasoning to the Attorney General's directive on the use of controlled substances to assist with suicide, the district court in *Oregon v. Ashcroft* found that it had jurisdiction to review the Ashcroft directive. 192 F. Supp. 2d at 1086.

The Ninth Circuit disagreed. Jurisdiction over the challenge to the Attorney General's directive, the court explained, was within the scope of § 877 because the Attorney General maintained that the directive was a "final determination" and because it ordered sanctions for violations of its provisions. *Oregon v. Ashcroft*, 368 F.3d at 1120. In support of this conclusion, the Ninth Circuit cited *Hemp Industries Ass'n v. DEA*, 333 F.3d 1082, 1085 (9th Cir. 2003), a case that held that the court of appeals had jurisdiction to hear a challenge of what the court considered to be a legislative rule. In Hemp Industries, however, the court declined to reach the question for which the *Oregon v. Ashcroft* panel cited it: whether § 877 granted court of appeals jurisdiction of challenges of interpretive rules or whether district court had jurisdiction in such challenges. See 333 F.3d at 1085. The reasons provided by the Ninth Circuit in *Oregon v. Ashcroft* do not address the scope of the key statutory terms "determinations, findings, and conclusions," nor the reasoning of the Supreme Court in *McNary* and cited by the district court.

The more persuasive interpretation of § 877 is that it does not apply to this action. The Supreme Court's reasoning in *McNary* is applicable here. Requiring

this matter to be reviewed directly in an appellate court, without the opportunity for fact-finding and without any factual record available from agency proceedings, would effectively deny meaningful review. That result could not have been intended by the drafters of § 877. Unlike the Attorney General's formal findings, determinations, and conclusions under Sections 811(a), 812(b), 823, and 824, the Raber letter is not the subject of a record of agency decision-making that could be available for judicial review at this point.

This analysis is also supported by *PDK Labs Inc. v. Reno*, 134 F. Supp. 2d 24, 29 (D.D.C. 2001). In *PDK Labs*, the plaintiffs sought relief against the DEA in a district court alleging that the DEA's refusal to issue a "letter-of-non-objection" or "LONO" violated the APA, plaintiff's due process rights under the Fifth Amendment of the U.S. Constitution, and some of the DEA's statutory duties. *Id.* at 27. The DEA expressed its refusal to issue the LONO in a letter stating that, under the relevant statutory provision, 28 U.S.C. § 971, the plaintiffs had no standing to pursue the LONO matter before the agency. The court found that § 877 did not apply because the agency's letter amounted to a final interpretation of § 971 but not a "final action under the [Chemical Diversion and Trafficking Act] as contemplated by § 877." *Id.* The Court of Appeals for the District of Columbia Circuit reviewed the case in a later phase without indicating that this jurisdictional finding was incorrect. See *PDK Laboratories, Inc. v. DEA*, 362 F.3d 786 (D.C. Cir. 2004).

In support of their argument that § 877 applies to the present case, defendants cite *John Doe, Inc. v. Gonzalez*, 2006 WL 1805685 (D.D.C. June 29, 2006). In *John Doe, Inc.*, the court considered what it referred to as the "vacuum of confusion" created by much of the case law discussed above, and determined that the action at issue in that case was within the reach of § 877. *Id.* at *19. While *John Doe, Inc.* suggests that § 877 applies to all final agency action of any form, the narrower issues presented by the actions in that case differ in critical respects from the letter campaign of which Novelty complains here. In other words, this court does not disagree with the result in that case, but only with some of the broader conclusions stated in the opinion.[4]

In *John Doe, Inc.*, the court considered whether § 877 applied to a challenge to a DEA decision to cancel and revoke the plaintiff's permit to import a substance. The plaintiff and the DEA disagreed as to whether the substance was properly designated a Schedule I or Schedule III substance. After having its first permit to import the substance approved, plaintiff applied for an additional permit. When a DEA official contacted plaintiff to investigate further, he phoned the plaintiff to say that the current application would be canceled and the previous approval revoked. He invited the plaintiff to submit more information in writing regarding its intent to import the substance. Plaintiff initially agreed to do

[4]The Attorney General's name was mis-spelled in the caption of *John Doe, Inc.* as "Gonzalez." The court noted the mis-spelling but then elected not to correct the error itself, see 2006 WL 1805685, at *1 n.1 (collecting cases and other authorities on court's power to correct error *sua sponte*). The opinion is formally reported with the mis-spelled name.

so, but plaintiff's president later sent a letter to the DEA's Office of Chief Counsel requesting that the phone decision be nullified. *Id.* at *10-*11.

The DEA responded by letter, explaining that the "final agency action" had occurred via the phone conversation, but also explaining that plaintiff could request a hearing or could waive a hearing and submit its position in writing to the agency. Plaintiff filed suit in federal court instead. The district court dismissed for lack of subject matter jurisdiction, offering two alternative holdings. First, the court found jurisdiction improper for lack of "final" agency action. *Id.* at *16-17. In the alternative, the court concluded, if the DEA's phone call amounted to final agency action, then § 877 would bar jurisdiction in the district court, effectively reasoning that § 877 applies to any final agency action, regardless of whether there is an available and reviewable record of agency decision-making. *Id.* at *17.

The court offered several reasons for its interpretation of § 877. First, the court explained that if the action at issue could be considered "final," then it "seem[ed] certain to meet the 'final determinations, findings, and conclusions' criteria" of § 877. Because the CSA provides one avenue for judicial review in a Court of Appeals only, the court reasoned, applying the traditional canon of *expressio unius est exclusio alterius*, the statute could not be construed to permit a district court to review any CSA-related determination by the DEA. *Id.* at *18-*20.

This reasoning is too broad and is in tension with *McNary*, where the Supreme Court reasoned that the act should be interpreted to authorize district court jurisdiction because the agency processes would not provide an adequate record, so that meaningful judicial review would require an opportunity to develop an adequate record in the district court. 498 U.S. at 496-97. The Supreme Court quoted with approval an amicus brief from the American Bar Association, observing that statutes providing for judicial review of agency actions only within the jurisdiction of a Court of Appeals "are traditionally viewed as warranted only in circumstances where district court factfinding would unnecessarily duplicate an adequate administrative record. . . ." *Id.* at 497.

Additionally, the argument that § 877 encompasses all CSA-related final agency actions is not, in fact, supported by the language of the provision. If Congress had intended for § 877 to apply to *all* CSA-related DEA actions, it could have included broader language. See *McNary*, 498 U.S. at 494 (explaining that if Congress had intended for § 210 of the INA to apply to plaintiffs' procedural challenge, it could have used broader language in the provision by modeling it after other broad provisions of the INA, which granted review of "all causes . . . arising under any of the provisions" of a program, or provisions governing veterans benefit claims which granted review "on all questions of law and fact"). While § 877 is perhaps more broadly worded than the statute in *McNary*, its use of the phrase "findings, determinations, and conclusions" is tied to other provisions in

the CSA the provide for formal agency procedures. The language does not show that jurisdiction of *all* final agency action lies exclusively in a Court of Appeals.

The *John Doe, Inc.* court also analogized interpretation of § 877 to other statutory schemes, explaining that courts have traditionally refused to allow plaintiffs to "circumvent clear statutory directives requiring direct petition to the courts of appeals." 2006 WL 1805685 at *21. Yet in each of the cases mentioned from the Seventh Circuit, the statutory review procedure provided the plaintiffs with appropriate, albeit later or perhaps slower, review of their claims on an adequate record of agency decision-making. See *Connors v. Amax Coal Co.*, 858 F.2d 1226, 1231 (7th Cir. 1988) (affirming dismissal of plaintiffs' claims for specific medical expenses under the Black Lung Benefits Act for lack of subject matter jurisdiction where statutory review procedure provided judicial review in the court of appeals only; despite overlap of plaintiffs' claims with other federal law, plaintiffs had shown no reason why statute-mandated review would be inadequate: "The focus is not on the agency's familiarity with particular legal questions, but on its ability to produce the kind of record that will permit adequate appellate review of the questions."); *General Finance Corp. v. FTC*, 700 F.2d 366 (7th Cir. 1983) (district court did not have jurisdiction under §§ 1331 or 1337 to review FTC investigation despite plaintiffs' claims that the investigation violated the McCarran-Ferguson Act; where sanctions could only be imposed against plaintiffs after district court review of FTC administrative subpoenas, and such review would determine the lawfulness of the investigation,

allowing plaintiffs to bring a declaratory suit would waste judicial resources and undermine statutory review). In this case, by contrast, Novelty does not have available an alternative mechanism for developing a record or obtaining judicial review, short of deliberately violating the requirements as interpreted by the DEA and defending itself in a proceeding where punitive sanctions could be very severe.

The strongest support for defendants' argument is provided in *Federal Communications Commission v. ITT World Communications, Inc.*, 466 U.S. 463, 468-69 (1984), in which the Supreme Court held that where the court of appeals was, by statute, the only proper forum for review of the agency action at issue, the district court had no subject matter jurisdiction over plaintiffs' claim that rulemaking by the agency was beyond its powers. Plaintiffs had first filed a rulemaking petition with the FCC regarding Consultative Process meetings in which the agency engaged with its foreign counterparts. The agency denied the petition. *Id.* at 465-66. Plaintiffs then filed an appeal of the agency denial in the Court of Appeals for the District of Columbia Circuit pursuant to 47 U.S.C. § 402(a) and 28 U.S.C. § 2342(1) (stating that the court of appeals had exclusive jurisdiction to review final FCC orders), and then filed a claim in the district court seeking essentially the same remedy as their rulemaking petition, a declaration that the rulemaking proceedings were ultra vires. See 466 U.S. at 466.

Rejecting plaintiffs' argument that the rulemaking record developed by the agency would not sufficiently permit the court of appeals to review their *ultra vires*

claim, the Supreme Court noted that any record deficiency could be remanded to the agency, citing *Harrison v. PPG Industries, Inc.*, 446 U.S. 578, 593-94 (1980) (considering proper review of EPA action) or referred to a special master, see 28 U.S.C. § 2347(b)(3). Where jurisdiction of the action at issue, the denial of the rulemaking petition, was so plainly granted to the court of appeals by statute, the functionality argument could not overcome the clear statutory command.

Construing the Court's reasoning in *ITT* with its later reasoning in *McNary*, *ITT* does not preclude the interpretation that Novelty's challenge lies outside of the jurisdictional reach of § 877. As already explained, § 877 does not unambiguously grant jurisdiction of Novelty's claim to the Court of Appeals as did the judicial review provision at issue in *ITT*. Without such clear direction, the *McNary* Court's emphasis in favor of providing meaningful judicial review prevails. Also, the formal action triggering the request for judicial review – the denial of the rulemaking petition – was more formal and specific than the alleged series of letters in this case.

The court in *John Doe, Inc.* also explained that policy considerations supported its interpretation of § 877 because permitting judicial review before the agency hearings and appeal process had completed would waste judicial and agency resources. 2006 WL 1805685 at *21. This reasoning was sound in *John Doe, Inc.*, in which plaintiffs were offered an appeals process that would have permitted meaningful review of their claims. The same is not true here; the

defendants have not shown any such path available to Novelty other than deliberate violations of the standards in the letter, which could lead to severe civil and even criminal sanctions. This difference between *John Doe, Inc.* and the issues facing this court warrants the opposite result in this case.

The court in *John Doe, Inc.* also distinguished the circumstances in that case from the critical factors that warranted district court jurisdiction in *McNary*. *Id.* at *22-*23. The *John Doe, Inc.* court emphasized that the language of § 877, which grants the court of appeals review of all "final determinations, findings, and conclusions," was broader than the language of § 210, which provided for judicial review of a denial of "special agricultural worker" ("SAW") status "only in the judicial review of an order of exclusion or of deportation." See *McNary*, 498 U.S. at 486 & n.6. The breadth of the language in § 877, the *John Doe, Inc.* court explained, demonstrated the intent that it apply to a wider range of acts than § 210. Additionally, the court in *John Doe, Inc.* found that *McNary* was not applicable to that case because "John Doe, Inc." could seek meaningful review in the court of appeals. 2006 WL 1805685 at *22.

Although the wording of § 877 is broader than the judicial review provision at issue in *McNary*, the discussion above demonstrates that the language of § 877 does not provide that it applies to any and every final action relating to the CSA. The *McNary* Court emphasized that judicial review in the district court was warranted because any other outcome would rob plaintiffs in that case of

meaningful judicial review of their claims. Similarly, in this case there has been no fact-finding, and so far there exists no administrative record beyond a copy of the Raber letter itself. Requiring Novelty to go forward in the Court of Appeals would effectively deny meaningful review. Although defendants argue that plaintiff has not exhausted its remedies within the DEA, they have not suggested what procedure, if any, exists to address plaintiff's improper rulemaking argument. Unlike the plaintiff in *John Doe, Inc.*, which had the opportunity to pursue the DEA's cancellation and denial of its permit applications via either a hearing or through the submission of materials stating its position to the agency, there is no sign in this case of any such avenue for appeal within the DEA or before the Attorney General. Ultimately, without jurisdiction in a district court in this case, plaintiffs are left without a forum for meaningful review of their claims, a disfavored result that was soundly rejected by the Supreme Court in *McNary*. Accordingly, § 877 does not bar this court's jurisdiction of review of the agency action at issue in this case.

II. *Finality*

The Administrative Procedure Act provides that only (1) agency actions made reviewable by statute and (2) final agency actions for which there is no other adequate remedy in a court are subject to judicial review. Preliminary, procedural, or intermediate agency actions are subject to review only in the review of the final agency action. 5 U.S.C. § 704. Defendants argue that the Raber letter was not a reviewable final agency action within the meaning of § 704.

The Supreme Court has emphasized that the finality requirement is to be applied in a "flexible" and "pragmatic" fashion. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149-50 (1967), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1980). To be "final," an agency action must generally satisfy two conditions: (1) it must mark the consummation or completion of the agency's decision-making process, meaning that it cannot be of a tentative character; and (2) the action must additionally be "one by which rights or obligations have been determined, or from which legal consequences flow." *Home Builders Ass'n of Greater Chicago v. U.S. Army Corps of Engineers*, 335 F.3d 607, 614 (7th Cir. 2003), quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997); see also *Role Models America, Inc. v. White*, 317 F.3d 327, 331-32 (D.C. Cir. 2003) (question is whether agency has imposed some kind of obligation, denied any right, or fixed a legal relationship); *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 435-36 (D.C. Cir. 1986) (finality inquiry looks to whether agency position is both definitive and has a direct impact on the day-to-day operations of the plaintiff).

Central to the finality determination is the tentative or definitive nature of the agency action at issue. In *Ciba-Geigy*, 801 F.2d at 435-36, the court found that an EPA letter to the plaintiff discussing a change in labeling requirements and the procedure for misbranding actions was final in part because the letter stated an unequivocal position with no ambiguity, gave no indication that it was subject to further agency consideration, and emphatically required immediate compliance. See also *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021-23

(D.C. Cir. 2000) (despite some qualifying language, agency guidance found to be final action; language imposing agency requirements was "unequivocal").

The Raber letter states in part:

> The below scenarios are provided in case you are storing List I chemical products (including over-the-counter ephedrine and pseudoephedrine items) and distributing them from satellite locations, such as commercial storage units, personal residences and or delivery vehicles. The Indianapolis District Office reminds all registrants that "any storage at, and distribution from, a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law".

Cplt. Ex. A. The letter does not provide a citation for the portion of the paragraph in quotation marks, and its source remains unclear. The letter goes on to state that the scenarios provided were meant to "help clarify overnight storage of List I chemical products . . . ." *Id.*

The first scenario pertains to overnight storage of List I chemicals by a sales representative who has obtained the chemicals but cannot return to the registered location because of a "long delivery route." The representative may keep the chemical products "in a locked secure vehicle" under a certain set of conditions, the letter explains. If kept under such conditions, the "DEA considers the List I chemical products to be in [ ] transit . . . ." The letter emphasized that "List I chemical products may NOT be stored in a locked and secure vehicle at a sales representative's home," where the chemical products would not be considered "in transit." *Id.*

The second scenario explains that sales representatives obtaining a "general order" of List I chemical products, as opposed to a specific pre-placed customer order, may not store such chemicals in locked secure vehicles overnight. If so stored, the letter states, such chemicals would not be considered "in transit," and any subsequent sale of such chemicals would be considered "distribut[ion] from an unregistered location," which the letter warns "is a violation of federal law." *Id.*

The third scenario provides that the DEA was aware that some companies shipped orders containing List I chemicals to representatives "at remote locations" and that this kind of "freight forwarding" was not permitted by any DEA provision. Finally, the letter provides a telephone number at the Indianapolis Diversion Group where the recipient can direct questions about the contents of the letter. *Id.*

Defendants argue that because the letter provides only "scenarios" regarding the proper storage of List I chemicals, it cannot be considered a final agency action, citing *Air Brake Systems, Inc. v. Mineta*, 357 F.3d 632 (6th Cir. 2004). In *Air Brake Systems*, the Chief Counsel of the National Highway Traffic Safety Administration and had written multiple letters regarding the compliance of plaintiff's products and had posted the letters on the agency's website. The Sixth Circuit held that the letters were not final agency actions. *Id.* at 635-37. The letters were written in response to consumer questions. Generally, the court explained, "agency letters based on hypothetical facts or facts submitted to the

agency, as opposed to fact-findings made by the agency, are classically nonfinal" because of the tentative nature of such actions. *Id.* at 638-39. Where the letters at issue stated tentative conclusions based on hypothetical facts submitted to the agency by the plaintiff and consumers, and where the terms of the letters provided as such, the court found no final action. See *id.* at 639-40 (letters included qualifying language such as: "Based on the literature provided to us . . . ." and "[plaintiff's product] also *appears* to lack any provision for illuminating a warning light") (emphasis in original).

Although the Raber letter provides "scenarios" with respect to List I chemical storage, the letter's language is definitive and unequivocal. It provides no qualifying language signifying that the letter was only an interim determination or that it was based on only limited information. Such cautions were repeatedly included in the letters and were critical to the court's different conclusion in *Air Brake Systems*. While the Raber letter states that it is a clarification of existing requirements, the language of the letter, which explains that certain actions are or are not permitted, are or are not in violation of federal law, is in no way tentative. The letter provides terms for proper storage and distribution of List I chemicals, indicates that storage practices that fail to comply with the terms of the letter violate federal law, and gives no indication that its content is in any way provisional.

The form of the letter, providing "scenarios" of apparently hypothetical facts, does not undermine the definitive nature of the agency's position articulated in the letter. "Once the agency publicly articulates an unequivocal position . . . and expects regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review." *Ciba-Geigy*, 801 F.2d at 435-36. The unequivocal nature of the letter, informing the regulated recipient that it will be violating federal law if it does not comply with the stated terms, demonstrates a demand for immediate compliance that indicates final action.

Defendants' argument that the action at issue, a letter outlining scenarios that demonstrate proper storage techniques, could not be final merely because of its form would create a loophole allowing agencies to avoid judicial review by issuing such letters instead of engaging in rulemaking according to the procedures required by the APA. The District of Columbia Circuit has recognized this danger in *Appalachian Power*:

> The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations, containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance and memoranda, explaining, interpreting, defining and often expanding the commands in the regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations. . . . An agency operating in this way gains a large advantage. "It can issue or amend its real rules, i.e., its interpretive rules and policy statements, quickly and

> inexpensively without following any statutorily prescribed procedures." Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 Admin. L. Rev. 59, 85 (1995). The agency may also think there is another advantage – immunizing its lawmaking from judicial review.

208 F.3d at 1020 (footnote omitted). While it is not at all clear that the Raber letter amounts to such an effort, a broad ruling that such letters can never amount to final agency action, using form as a proxy for finality (or non-finality), could allow such evasion of judicial review.

Defendants also argue that, because the letter at issue was written by Raber, Indianapolis Diversion Supervisor, who is not permitted by agency rule to take final actions, the letter cannot be final for purposes of review under § 704. See Def. Br. at 13. This court denied Novelty's discovery requests in its February 3, 2006 entry in part because at that stage of the case, it appeared that the intra-agency details sought by Novelty were not so essential to the finality determination. See Docket No. 58.

Courts determining the finality of agency action have tended to focus on the language and character of the action at issue, see *Air Brake Systems*, 357 F.3d at 638-39, and whether the issuing agency official is subordinate or has authority to engage in such an act is a necessary factor for consideration. *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992) ("Agency action is not final if it is only 'the ruling of a subordinate official,' or 'tentative.'"); *Western Illinois Home Health Care, Inc. v. Herman*, 150 F.3d 659, 663 (7th Cir. 1998) (fact that agency official

taking action at issue was a "subordinate official . . . might suggest tentativeness or lack of finality"); *Air Brake Systems*, 357 F.3d at 640.

Novelty does not argue, however, that Raber's letter alone amounts to final agency action. Novelty argues that the letter was part of a coordinated nationwide effort to alter storage standards of List I chemicals. Defendants have argued that Raber himself was not delegated authority to promulgate rules relating to the registration of distributors of List I chemicals, or to suspend, deny, or revoke such registration. This assertion does not address, however, whether Raber's letter is part of a nationwide effort on the part of the agency to alter List I chemical storage requirements. Defendants have provided no evidence on this score, and the court earlier denied plaintiff's request for discovery on the subject. In light of the parties' arguments, the limited record before the court, and the standard of review on defendants' motion to dismiss, the court cannot find at this stage that the requirements articulated by the letter were merely the pronouncements of a subordinate official and therefore not "final" for present purposes. Further factual development may show that the Raber letter was not final, but the court cannot reach that conclusion at this point in the litigation. Now that the other issues presented by the parties' jurisdictional arguments have been resolved, it now appears proper to permit Novelty to pursue discovery regarding such facts.

Defendants also claim that Novelty seeks here nothing more than pre-enforcement judicial review of an agency investigation. Although Novelty initially

sought to quash the Arkansas subpoena, both the subpoena and Novelty's claim relating to it have been withdrawn. At this later point in the case, Novelty's claims consist only of challenges to the letter as improper rulemaking. The defendants' argument that Novelty's challenge amounts to an impermissible attempt to halt an administrative investigation, citing *General Finance Corp. v. FTC*, 700 F.2d 366, 368-69 (7th Cir. 1983), is no longer viable. The allegedly improper rulemaking gives the Novelty the unpleasant choice between complying with the new rule at significant cost to its business or trusting its judgment that the rule is improper, continuing its conduct, and facing the prospect of a substantial penalty.

Both sides rely on the Seventh Circuit's decision in *Abbs v. Sullivan*, 963 F.2d 918, 926 (7th Cir. 1992). In *Abbs*, the court found no jurisdiction over a scientist's claim challenging the investigative procedural rules followed by the Office of Scientific Integrity at the National Institute of Health ("NIH") in investigating claims of scientific misconduct. In investigating allegations against the plaintiff, the NIH began to collect information and placed the plaintiff's name on its "ALERT" system. *Id.* at 921. The Seventh Circuit explained that the issuance of a rule of conduct is reviewable where there is no other judicial remedy. *Id.* at 925-26, citing 5 U.S.C. § 704. By challenging only procedural rules governing the investigation as to whether he had committed misconduct, the plaintiff in *Abbs* could show no dilemma, harm, or risk that he faced by complying with the investigation and appealing any adverse results. As such, his action was not reviewable. The court explained:

> A challenge to administrative action, whether the action is denominated a rule or complaint, falls outside the grant of jurisdiction in section 10(c) of the Administrative Procedure Act when the only harm the challenger seeks to avert is the inconvenience of having to go through the administrative process before obtaining a definitive declaration of his legal rights.

Id. at 927. As such, claims of hardship by a plaintiff seeking review of agency action are not, taken alone, compelling arguments in favor of immediate review. *Air Brake Systems*, 357 F.3d at 644-45 ("adverse economic effects accompany many forms of indisputably nonfinal government action."); *DRG Funding Corp. v. Secretary of Housing and Urban Development*, 76 F.3d 1212, 1215 (D.C. Cir. 1996) (claims of hardship, without more, will rarely overcome the finality and fitness concerns implicated by seeking review of merely tentative decisions).

More relevant to this case, however, the court distinguished the procedural challenge of the plaintiff in *Abbs* from a challenge to a rule of conduct:

> There is, though, a critical difference between challenging a rule of conduct that carries sanctions for its violation and a rule of procedure . . . that specifies what sanctions, and how, are applicable to (alleged) misconduct already committed. If the rule of conduct with sanctions attached cannot be challenged in advance of violating it, the people subject to it are placed in a dilemma; comply with a rule that harms them and that they believe to be invalid or violate the rule at the risk of incurring a heavy penalty (criminal in both *Abbott Laboratories* and *Frozen Food Express*) if they've guessed wrong and the rule is upheld in the penalty proceeding. . . . In such a case, the judicial remedy that comes at the end of the penalty proceeding is inadequate in the familiar equity sense that permits, for example, the issuance of a preliminary injunction in a damages case upon showing irreparable harm. . . . So the rule can be challenged directly, in a separate proceeding such as the one here.

Abbs, 963 F.2d at 926 (citations omitted). Novelty's challenge to the requirements articulated in the Raber letter presents the kind of claim for judicial review of a rule of conduct contemplated by *Abbs*. Novelty claims that the standards articulated in the Raber letter would require it either to alter dramatically the way it does business or to defy the Raber letter's clear directions and face serious penalties for violating federal law if Novelty's judgment about the invalidity of such standards is inaccurate. This dilemma, as explained in *Abbs*, weighs in favor of finding that the action is reviewable and that jurisdiction exists in this case.

The DEA also appears to argue that jurisdiction is improper because Novelty has failed to exhaust its administrative remedies by petitioning for the repeal of the alleged new ruled articulated in the Raber letter under 5 U.S.C. § 553(e), which provides that agencies must provide interested persons with the opportunity to petition for the issuance, amendment, or repeal of a rule. The APA limits the doctrine of exhaustion of administrative remedies to requiring only those procedures that are mandated by statute or rule. 5 U.S.C. § 704; *Darby v. Cisneros*, 509 U.S. 137 (1993); see also *Alto Dairy v. Veneman*, 336 F.3d 560, 568 (7th Cir. 2003). Although § 553(e) requires the agency to provide interested persons the opportunity to petition for the repeal of a rule, it does not state that an interested entity must appeal the rule within the agency before review, or that the rule is inoperative during the review proceedings. See *Alto Dairy*, 336 F.3d at 568-69, citing *Darby*, 509 U.S. at 146. Additionally, the First Circuit has observed that a rule may be challenged either after the rulemaking proceeding, or after an

appeal within the agency, indicating that § 553(e) does not compel a plaintiff to exhaust administrative remedies by appealing to the agency before seeking review of a rule. See *Sherwin v. Secretary of Health and Human Services*, 685 F.2d 1, 4-5 (1st Cir. 1982). Defendants have not pointed to any other agency rule or relevant statute requiring additional appeals within the agency.

Conclusion

For the foregoing reasons, defendants' motion to dismiss, Docket No. 30, is hereby DENIED. Further factual development in this case may bear on whether this court has subject matter jurisdiction. Accordingly, Novelty must be permitted to pursue discovery pertaining to the authority for the issuance of the Raber letter. Counsel shall promptly confer to develop a plan for such discovery. If no agreement is reached, the court will confer with counsel and address the subject. Additionally, the court orders that Attorney General Alberto Gonzales be substituted for former Attorney General Ashcroft as a defendant in this matter.

So ordered.

Date: August 15, 2006

DAVID F. HAMILTON, JUDGE
United States District Court
Southern District of Indiana

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